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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,598	02/10/2004	William W. Bachovchin	2002941-0100	3284
24280	7590	10/24/2005	EXAMINER	
CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			LUKTON, DAVID	
		ART UNIT	PAPER NUMBER	
		1654		

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/775,598	BACHOVCHIN ET AL.
Examiner	Art Unit	
David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 15 August 2005.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 29-44 is/are pending in the application.  
4a) Of the above claim(s) 44 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 29,31-36,38-40,42 and 43 is/are rejected.

7)  Claim(s) 30,37 and 41 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

Applicants' election of Group I (claims 29-43) is acknowledged, as is the elected specie:

Pro-Pro-Pro-boroPro

wherein each proline is of the "L" configuration, and the *alpha*-carbon atom of the boroPro moiety is also of the "L" configuration.

Claims 29-44 remain pending.      Claims 29-43 are examined in this Office action; claim 44 is withdrawn from consideration.

◆

Applicants are required to submit another copy of the abstract.      It is noted that pursuant to a preliminary amendment filed 7/15/04, applicants directed that the originally filed abstract be replaced with another.      However, an abstract should be placed on a page on which no other information (e.g., comments or directives) are present; the relevant title (e.g., ABSTRACT OF THE DISCLOSURE) should be placed at the top of the page.      At present, neither of the foregoing requirements has been met.

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Claim 34 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of USP 6825169.      Although the conflicting claims are not identical, they are not patentably distinct from each other.

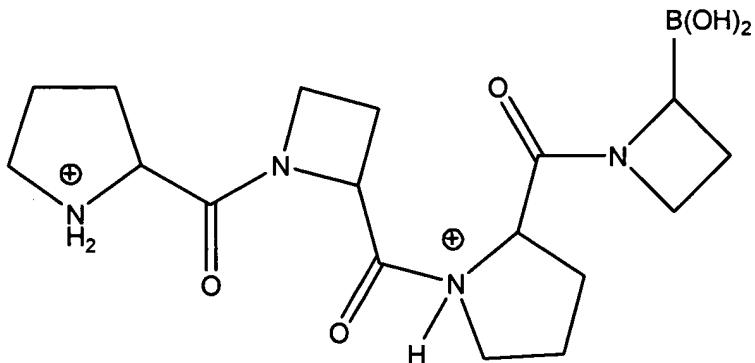
Claim 1 of USP '169 are drawn to a mixture of stereoisomers, whereas claim 29 of the instant application is drawn to "a compound". According to one interpretation, the term "compound" would mean one stereoisomer (this interpretation is not universal, however). As indicated, claim 34 is drawn to a mixture of compounds; only one of the compounds present in the mixture is specifically identified. The first point to be made is that pharmaceutical compositions are well known to drug formulation specialists of ordinary skill, and one such drug formulation specialist in possession of the '169 patent would immediately regard compositions containing the claimed compounds (of the '169 patent) as obvious. In other words, if applicants were now claiming a composition containing the same mixture of stereoisomers as claimed in the '169 patent, such a claim would be rendered obvious. That is not what is now being specifically recited in the claims; but claim 34 encompasses this nonetheless. That is, if a drug formulation specialist took a mixture of claim 1 (of the '169 patent) and combined it with a pharmaceutically acceptable carrier, he (or she) would be in possession of the composition of claim 34. The reason why this is true is not because one would necessarily want to take a pure compound of instant claim 29 and combine it with a stereoisomer; rather the reason why one would want to have a mixture of stereoisomers is simply that a tedious and laborious purification process (of stereoisomers) could be avoided thereby.

Thus, claim 34 is rendered obvious.

♦

Claims 34, 42, 43 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 34 is drawn to a compound, yet is described as a mixture of a compound and a carrier. Is claim 34 drawn to a carrier or a composition? If a composition is intended, this should be made clear.
- In claim 42, it is recited that each broken line can represent a bond to an “R” group. Suppose that R is propyl, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup> are each hydrogen, H’ is also hydrogen, and p is 1. For the case of each broken line representing a bond to the propyl group, the resulting structure would be the following:



Note that the proline nitrogen atom is protonated, but the nitrogen atoms in each of the azacyclobutane rings are not. Is this intended?

- Continuing with claim 42, suppose that “R” is hydrogen. As stated, broken line can represent a bond to an “R” group. For the case of R representing hydrogen, what is the resulting structure?

\*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 31-36, 38-40, 42, 43 are rejected under 35 U.S.C. §102(b) as being anticipated by Bachovchin (USP 4,935,493).

Bachovchin discloses the following compounds:

Ser-Thr-Pro-Pro-boroPro (col 5, line 51)

boroPro-pinacol (col 8, line 63)

Claim 29 is anticipated for the case of "m" being 1, "A" being threonine, and A<sup>1</sup> being proline. Because of the term "having" (in line 1 of claim 29), an additional amino acid can be added to the N-terminus.

Also disclosed are the following compounds (table I, col 10):

Ala-boroPro

Pro-boroPro

These compounds anticipate claims 42-43 for the case of "p" being zero

◆

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800